REMARKS

Priority

Applicants note the objection raised by the Examiner regarding the priority status of the application (Office Action, pg. 2). The specification is presently amended to provide a more detailed priority claim.

Specification

The Applicants also note the objection raised by the Examiner regarding the topical headings within the present application (Office Action, pg. 2-3). The specification is presently amended to provide the required topical headings.

The specification is also amended to include a section entitled "Description of the Drawings." Descriptions for Figures 1-4 are added in this section. This text describing these figures appears at page 4, line 37 to page 5, line1 in the unamended specification, and the text indicating which Examples are shown in each figure are indicted on the drawings as filed. As such, this section added by amendment does not constitute new matter.

Claim Rejections

Claims 12 - 25 are pending in the Application. All claims are presently rejected. For the sake of clarity, the Examiner's rejections are summarized in the order they are herein addressed:

1) Claim 25 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite;
2) Claims 12, 16-18, 20, and 23-25 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by Clark (U.S. Patent No. 4,005,191);
3) Claims 12, 14-17 and 20-24 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Futami *et al.* (U.S. Patent No. 4,740,245,);
4) Claims 12, 14-24 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Futami *et al.* (U.S. Patent No. 4,740,245) in view of Futami *et al.* (U.S. Patent No. 5,051,130);
5) Claims 12, 14-17 and 20-25 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Futami *et al.* (U.S. Patent No. 4,740,245) in view of Remington: The Science and Practice of Pharmacy, 19th Edition;

6) Claims 12-15 and 17-24 are rejected under 35 U.S.C. § 103(a), as allegedly being unpatentable over Dietz (U.S. Patent No. 5,585,117) in view of Scafidi (U.S. Patent 5,683,683).

1) Claim 25 Is Not Indefinite

The Examiner rejects Claim 25 under 35 U.S.C. §112(2) as being indefinite. (Office Action, pg. 3). In particular, the Examiner states: "Accordingly, the term "liquid paraffin" is indefinite because it is directed to liquid form of paraffin. The specification does not clearly redefine the scope of such term. Nor does it clearly limit the scope of such term to only viscous, pliable liquid of paraffin. Accordingly, the term "liquid paraffin" in view of its based claim 12 appears ambiguous." Office Action, pg. 3. Applicants respectfully disagree. Indeed, the Specification provides a definition of waxes that are preferred for the purpose of the invention as: "paraffins which are liquid at room temperature and comply with DAB (Deutsches Arzneimittelbuch [German Pharmacopeia], for example paraffinum liquidum and paraffinum perliquidum." Specfication, page 3, lines 11-14. Furthermore, wax in a liquid form clearly falls within the definition of "wax" asserted by the Examiner ("a viscous, solid or pliable liquid substance of mineral origin", Office Action, pg 3). Applicants' use of the term liquid wax to indicate a liquid form of a wax thus is consistent with both the definition provided in the specification and with the meaning of "wax" asserted by the Examiner. As such, the use of the term "liquid paraffin" within Claim 25 is not indefinite or ambiguous. Applicants respectfully request this rejection be withdrawn.

2) Claims 12, 16-18, 20, and 23-25 Are Not Anticipated

The Examiner rejects Claims 12, 16-18, 20, and 23-25 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,005,191 (hereinafter "Clark"). In particular, the Examiner alleges: "Clark discloses methods of treating various types of skin wounds comprising applying to a wound topical compositions comprising petrolatum, a metal hydroxide such as magnesium hydroxide, an additional substance such as lanolin base in amounts of about 50% by weight." Office Action, pg. 4.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The Examiner alleges that each of the limitations inherent within Claims 12, 16-18, 20, and 23-25 are anticipated by the Clark patent. Office Action, pg. 4-5. Applicants respectfully disagree.

Clark does not teach each and every claim element within Claims 12. Claims 16-18, 20, and 23-25 are method claims dependent upon Claim 12. Claim 12 provides in step (b) that the composition is applied to a ***bone wound*** as a dressing. The topical ointment provided by Clark, however, is for treating ***skin injuries***. The Clark patent does not teach the use of compositions in the treatment of bone wounds. Indeed, the Clark patent thoroughly defines "skin," but does not include "bone" within its description. Clark, Column 1, Lines 27-68 and Column II, Lines 1-30. Indeed, a thorough description of bone and the regeneration processes of bone are detailed in U.S. Patent No. 5,585,117 (cited by the Examiner in an alternate rejection; see below). A comparison of the Clark definition of skin, and the U.S. Patent No. 5,585,117 definition of bone highlights the stark differences between bone and skin. As such, the Clark patent does not teach each and every element of Claims 12, 16-18, 20, and 23-25, and thus does not anticipate these claims. Applicants respectfully request this rejection be withdrawn.

The Claims Are Non-Obvious

The law is clear that three basic criteria must be met to establish a *prima facie* case of obviousness: (MPEP ¶2143):

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest *all* the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure (*emphasis added, In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Failure to establish **any one** of these three requirements precludes a finding of a *prima facie* case and, without more, entitles Applicants to allowance of the claims at issue. Applicants assert that the pending claims are nonobvious.

3) Claims 12 and 14-17, 20-24 Are Non-Obvious

The Examiner rejects Claims 12, 14-17, and 20-24 under 35 U.S.C. §103(a) as allegedly being obvious in light of U.S. Patent No. 4,740,245 (hereinafter "'245"). The Examiner admits that that "Futami does not explicitly teach methods of treating a wound" but asserts that "It would have been obvious to one of ordinary skill in the art at the time of the invention to employ Futami's composition for treating a wound in the surface of a bone, because as taught by Futami, the intended purpose of Futami's compositions is treating root canal filling and root canal is a wound in a bone." Office Action, pg. 5-6. Applicants respectfully disagree.

The Examiner's statement that a root canal is a wound in a bone (Office Action, pg. 6) is incorrect. As detailed at www.dentalreference.com (see Appendix A) a root canal is a canal in the lower part of the tooth where the nerves and blood vessels pass. The tooth by itself is one of the hard bony appendages that are born on the jaw, ***but is not a bone*** in terms of the skeleton (see Merriam-Webster OnLine Dictionary excerpt at Appendix B). Indeed, this distinction was noted in prosecution of the present Application, when restriction of the claims was required in the Office Action mailed March 10, 2003. That Office Action distinguished between the current Claims 12-25 (Group I, elected), which are directed toward treatment of bone wounds and Claims 26-35 (Group II, canceled in the Response filed on April 10, 2003), which were drawn to methods of filling root canal in oral surgery. As noted in the Office Action of March 10, 2003 requiring restriction, "Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and effects."

The presently claimed invention provides that the composition is applied to a *bone wound* as a dressing. The '245 patent does not teach application of the disclosed compounds to bone wounds. The Examiner has previously asserted that use of the present methods in the treatment of root canals is a *distinct invention having different function and effect.* As such, the Examiner has therefore has provided no basis for asserting that Claims 12, 14-17, and 20-24 are obvious in view of the '245 patent. Applicants respectfully request this rejection be withdrawn.

4) Claims 12 and 14-24 are Non-Obvious

The Examiner rejects Claims 12 and 14-24 under 35 U.S.C. §103(a) as being unpatentable over the '245 Patent in view of U.S. Patent No.: 5,051,130 (hereinafter '130). In

particular, the Examiner alleges: "it would have been obvious to one of ordinary skill in the art at the time of invention to use Futami's '245 compositions, as taught in his example 2, and add a vegetable oil or caster oil to improve the handling and its setting characteristics, because both Futami '245 and '130 essentially are used for the same purpose and Futami '130 provides that vegetable oils or caster oil improve handling of the dental paste compositions. Subsequently, as reasoned in paragraph 5, it would have been obvious to one of ordinary skill in the art at the time of invention to employ such dental compositions for their own intended use and treat wounds in the jaw bone." Office Action, pgs. 7-8. Applicants respectfully disagree.

As discussed above, the '245 patent does not teach application of the disclosed compounds to bone wounds. The combination of '245 with '130 does not cure this deficiency. Futami's '130 patent relates explicitly to filling compositions for dental repair. '130 does not teach application of the disclosed compounds to bone wounds, and the Examiner's assertion that one of skill in the would be motivated to use dental filling materials to treat wounds in a *jaw bone* is wholly without support. For the reasons recited above and incorporated here, the teachings of '245 regarding root canal treatments do not provide a teaching of bone wound treatments. Thus, the combined references fail to teach or suggest all of the claim limitations of the present claims. As such, Claims 12 and 14-24 are non-obvious in view of the combination of the '245 and '130 patents and Applicants respectfully request this rejection be withdrawn.

5) Claims 12, 14-17 and 20-25 Are Non-Obvious

The Examiner rejects Claims 12, 14-17 and 20-25 under 35 U.S.C. §103(a) as being unpatentable over the '245 Patent in view of Remington: The Science and Practice of Pharmacy, 19th Edition (hereinafter Remington). The Examiner alleges: "Futami fails to explicitly teach liquid paraffin...thus as petrolatum, soft paraffin, white petroleum jelly, white soft paraffin are art recognized functional equivalents, it would have been obvious to one of ordinary skill in the art at the time of invention to replace paraffin's of Futami '245 with petrolatum or petroleum jelly, because the ordinary skill in the art would have had a reasonable expectation of success in observing the same benefits." Office Action, pg. 8. Applicants respectfully disagree.

As discussed above and for the reasons recited above and incorporated here, the teachings of '245 regarding root canal treatments do not provide a teaching of bone wound treatments. The combination of '245 with Remington does not cure this deficiency. Remington provides

teachings of some properties of petrolatum and other compounds, but does not teach application of the disclosed compounds to methods of treating bone wounds. Thus, the combined references fail to teach of suggest the all of the claim limitations of the present claims. As such, Claims 12, 14-17 and 20-25 are non obvious in view of the combination of the '245 and Remington and Applicants respectfully request this rejection be withdrawn.

6) Claims 12-15 and 17-24 Are Non-Obvious

The Examiner rejects Claims 12-15 and 17-24 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,585,117 (hereinafter '117) in view of U.S. Patent No. 5,683,683 (hereinafter '683). In particular, the Examiner states: "Dietz meets all the limitations of pending claims, except that it employs compositions that contain neatsfoot oil rather than vegetable oils, fasts or waxes of the instant claims 12, 17-19. However, as shown by Scafidi, neatsfoot oil, jojoba oil, castor oil, and sunflower oil are art-recognized equivalents. Accordingly, absence of showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to substitute neatsfoot oil of Dietz with any of white petrolatum, jojoba oil, castor oil or sunflower oil, lanolin oil, because, as suggested by Scafidi, they are art recognized equivalents and the ordinary artisan would have had a reasonable expectation of observing similar effects when using one in place of the other." Office Action, pg. 9. Applicants respectfully disagree.

Indeed, as indicated in the accompanying Declaration of Dr. Lück[1] (Lück Declaration; attached hereto at Tab 1), an inventor of the presently claimed invention, the present invention has properties that are surprising, in view of the prior art and knowledge in the art. These surprising properties include the fact that saponification of the composition does not occur, and furthermore, that mixtures of the presently claimed invention are stable over long time periods (*See,* Lück Declaration, page 1 and 3, as well as Figures 1 and 2). As Dr. Lück indicates, one of skill in the art would expect that mixing oleum pedum tauri (neatsfoot oil) and $Ca(OH)_2$ would be unstable, primarily due to saponification of the triglycerides. In addition, the Dietz reference cited against the present claims also indicates that mixtures of oleum pedum tauri and $Ca(OH)_2$ are unstable and must be used immediately after mixing in order to avoid hydrolysis of the oleum

[1] This Declaration was initially provided in U.S. Patent Application No.: 09/169,559, issued as U.S. Patent No.: 6,541,040. This is the parent case of the present application. The subject matter of this Declaration involves the same invention, and is equally applicable in response to the present rejection.

pedum tauri (*See,* U.S. Patent 5,585,117, col. 3, lines 1-11). Dr. Lück's Declaration confirms this. For instance, as described in Example 7 of the Lück Declaration, Dr. Lück observed that after 12 months of storage, a mixture of petrolatum, oleum pedum tauri, and $Ca(OH)_2$ is unstable. The paste was extremely thick and could not be extruded out of a syringe. Other Examples in the Lück Declaration provide additional confirmation.

In view of the teachings of the Dietz reference, which *teaches away* from the presently claimed invention and Dr. Lück's Declaration, it is clear that the presently claimed invention is nonobvious. Indeed, as the art cited by the Examiner indicates that mixtures of neatsfoot oil and $Ca(OH)_2$ are unstable, one of skill in the art would expect that the composition of the present invention would also be unstable, as hydrolysis would be expected to occur in the same manner as with neatsfoot oil. Surprisingly, this detrimental hydrolysis does not occur in the present invention. Thus, the methods and compositions of the presently claimed invention could not be predicted by the prior art cited, and are unobvious, as the substitution of other compounds in the compositions and methods of the presently claimed invention does not provide a reasonable expectation of success in producing the presently claimed invention.

Furthermore, the presently claimed invention provides unexpected advantages over compositions of the prior art and succeeds where the prior art cited fails (*i.e.,* producing and utilizing mixtures of metal hydroxides and wax that exhibit a delay in alkalinity release, etc.). The Specification teaches that "[w]here the vegetable oils, fats or waxes show a certain tendency to hydrolysis in the presence of a metal hydroxide, which would be intrinsically deleterious for adequate stability on storage, *surprisingly* the synthetic waxes or their oxidates present in the mixture according to the invention stabilize the complete mixture, leading to adequate stability on storage" (Specification, page 3, lines 31-37, *emphasis added*). As the prior art cited *teaches away* from the presently claimed invention, Applicants submit that the presently claimed invention is unobvious[2]. Indeed, as indicated in Dr. Lück's Declaration, the compositions of the presently claimed invention exhibit surprising characteristics. Based on the above, Applicants

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[2] As indicated in the MPEP (2141.02), prior art references must be considered in their entirety, including portions that would lead away from the claimed invention (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed Cri. 1983), *cert. denied*, 469 U.S. 851 (1984)).

assert that the Claims 12-15 and 17-24 are unobvious, and respectfully request that this rejection be withdrawn.

CONCLUSION

All grounds of rejection of the Office Action of July 02, 2003 have been addressed and reconsideration of the application is respectfully requested. It is respectfully submitted that Applicants' claims should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

Dated: December 2, 2003

Mary Ann D. Brow
Registration No. 42,363
MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105

DETAILED DESCRIPTION OF THE INVENTION

On page 4, after line 34, please insert the following text:

EXAMPLES

On page 8, line 1, please change the text as follows:

~~Claims~~CLAIMS

We Claim:

On page 9, at line 1, please change the text as follows:

~~Abstract~~ABSTRACT

Nerves - relay signals such as pain to and from your brain.

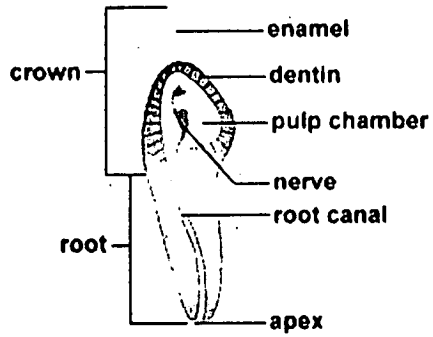
Periodontal Ligament - the connective tissue which surrounds the tooth and connects it to bone.

Pulp - located in the center of the tooth, it contains the blood vessels and nerves.

Root canal - canal in the root of the tooth where the nerves and blood vessels pass.

Tooth Structure

The portion of the tooth visible in the mouth is called the crown. The crown is covered with enamel, which is highly calcified bone; it serves as the protective layer of the tooth. Enamel is made up of millions of tiny rods which form the framework of the tooth. Enamel is thickest near the biting surface of the tooth and thinnest near the gumline. The color of enamel varies from yellow to white depending on its translucency. The more translucent it is, the more the yellowish layer of dentin underneath shows through. The enamel portion of the tooth has no feeling. Even though it is extremely hard, it can wear away due to attrition (wear) and may fracture due to stress.



list of site diagrams

The layer underneath the enamel is the dentin. It forms the bulk of the crown and the roots. Dentin is softer than enamel and carries sensations, such as temperature and pain, to the pulp.

The pulp comprises the innermost portion and is the only soft tissue of the tooth. It supplies nutrients to the tooth and its nerve endings transmit sensations such as pain and temperature.

Cementum forms a very thin layer over the roots of the tooth and is similar to bone. It's yellowish in color and carries sensations to the pulp.

Main Entry: **[1]bone**
Pronunciation: ˈbōn
Function: *noun*
Usage: *often attributive*
Etymology: Middle English *bon*, from Old English *bAn;* akin to Old High German & Old Norse *bein* bone, and perhaps to Old Irish *benaid* he hews
Date: before 12th century
1 a : one of the hard parts of the skeleton of a vertebrate **b** : any of various hard animal substances or structures (as baleen or ivory) akin to or resembling bone **c** : the hard largely calcareous connective tissue of which the adult skeleton of most vertebrates is chiefly composed

Main Entry: **tooth**
Pronunciation: 'tüth
Function: *noun*
Inflected Form(s): *plural* **teeth** /'tEth/
Etymology: Middle English, from Old English *tOth;* akin to Old High German *zand* tooth, Latin *dent-, dens,* Greek *odont-, odous*
Date: before 12th century
1 a : one of the hard bony appendages that are borne on the jaws or in many of the lower vertebrates on other bones in the walls of the mouth or pharynx and serve especially for the prehension and mastication of food and as weapons of offense and defense **b** : any of various usually hard and sharp processes especially about the mouth of an invertebrate

Declaration of

Dr. sc. Rainer Lück
Norderstraße 81
25436 Tornesch

Hamburg, 20th of November 2000

my name is Rainer Lück and I am the head of research and development of the DMG Dental-Material Gesellschaft mbH in Hamburg. I studied chemistry at the Humboldt-University of Berlin from 1070 to 1974 closing with the Diploma in the field of theoretical (quantum) chemistry with a monograph titled "Quantum chemical Calculations to interpret EPR-parameters". From 1974 – 1991 I worked as a chemist on the Central Institute of Anorganic Chemistry of the Academy of Sciences of the GDR. In 1980 I the Ph.D. in chemistry in the field of inorganic chemistry with a monograph titled "Investigations of the Chlorination Reactions of Metakaoline in the heterogeneous System solid / gas" and the Ph.D. of sciences (Dr. sc. Is the GDR-equivalent to the Habilitation in the Federal Republic of Germany) in the field of physical chemistry especially of magnetic resonance spectroscopy with a monograph titled "ESR investigations of chemically, thermal an pressure induced structural changes in inorganic solids".
In this time I was the head of different project teams and the vice head of the department of solid state chemistry. From 1991 to 1994 I worked in the field of magnetic resonance spectroscopy at the University of Hamburg. I am the author of more than 150 publications, papers and posters in national and international journals and congresses and worked some years in the editor board of the journal "Chemical papers" of the Slovacian Academy of Sciences.

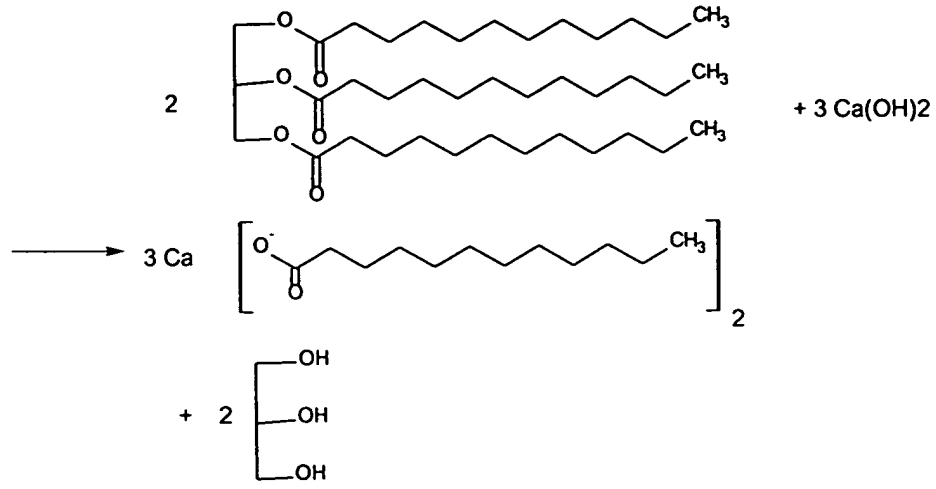
Explanations and tests concerning application US 09/169,559

The mixture of petrolatum, oleum pedum tauri and $Ca(OH)_2$ is unstable due to the chemical reaction of $Ca(OH)_2$ and oleum pedum tauri.
Oleum pedum tauri consists of esters of glycerol and long chain fatty acids.
In contact with $Ca(OH)_2$ a saponification reaction takes place (reaction 1).
This saponification can be detected by IR-spectroscopy and by change in viscosity. The viscosity increases and the pastes become extremely thick.
In the infrared spectrum the absorption of the ester-group at 175O cm^{-1} decreases and absorption of the carboxylic acid salt at 1570 and 1590 cm^{-1} increases.

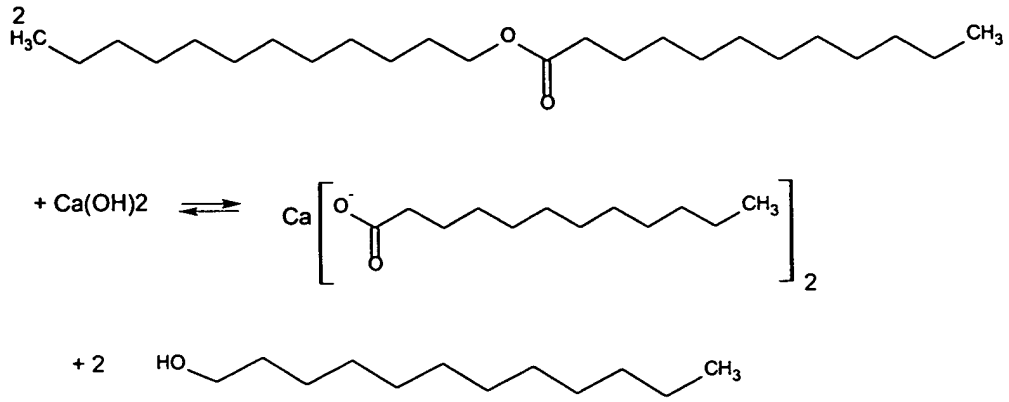
Jojoba oil is an ester of long chain alcohol and long chain fatty acids. We would expect the same reaction mechanism (reaction 2) to occur as in reaction 1. Much to our surprise the pastes with jojoba oil showed markedly an improved long term stability.

The reaction mechanisms were drawn with lauric acid as an exemplary fatty acid and dodecylalcohol as an exemplary long chain alcohol.

Reaction 1



Reaction 2



The numbering of the following additional examples adheres to the numbering of the application US 09/169,559

Example 6

35 g petrolatum (DAB 10), 45 g jojoba oil and 20 g $Ca(OH)_2$ are dispersed and stored in a syringe. The paste has a weak consistence.

Example 7

35 g petrolatum (DAB 10), 45 g oleum pedum tauri and 20 g $Ca(OH)_2$ are dispersed and stored in a syringe. The paste has a weak consistence.

After 12 months the consistence of paste 7 became extremely thick and it was not possible to extrude this material out of a syringe.
After 12 months the consistence of paste 6 was still weak and it was possible to extrude this material from a syringe. After 36 months the consistence of paste 6 became a little bit less weak, but it was still possible to extrude this material from the syringe.

	Consistence 0 month	Consistence 12 months	Consistence 36 months
Example 6	Weak extrudable	Weak extrudable	Less weak extrudable
Example 7	Weak extrudable	Hard not extrudable	Hard not extrudable

Example 8

20 g petrolatum (DAB 10), 20 g oleum pedum tauri and 60 g $Ca(OH)_2$ are dispersed and stored in a syringe. The paste has a weak consistence.

The mixture was stored at room temperature for one year.
IR spectra were taken immediately after preparation and after 12 months storage at room temperature.
As shown in figure 1 the absorptions between 15000 and 1600 cm^{-1} increased .very strongly indicating a high degree of saponification.

Example 9

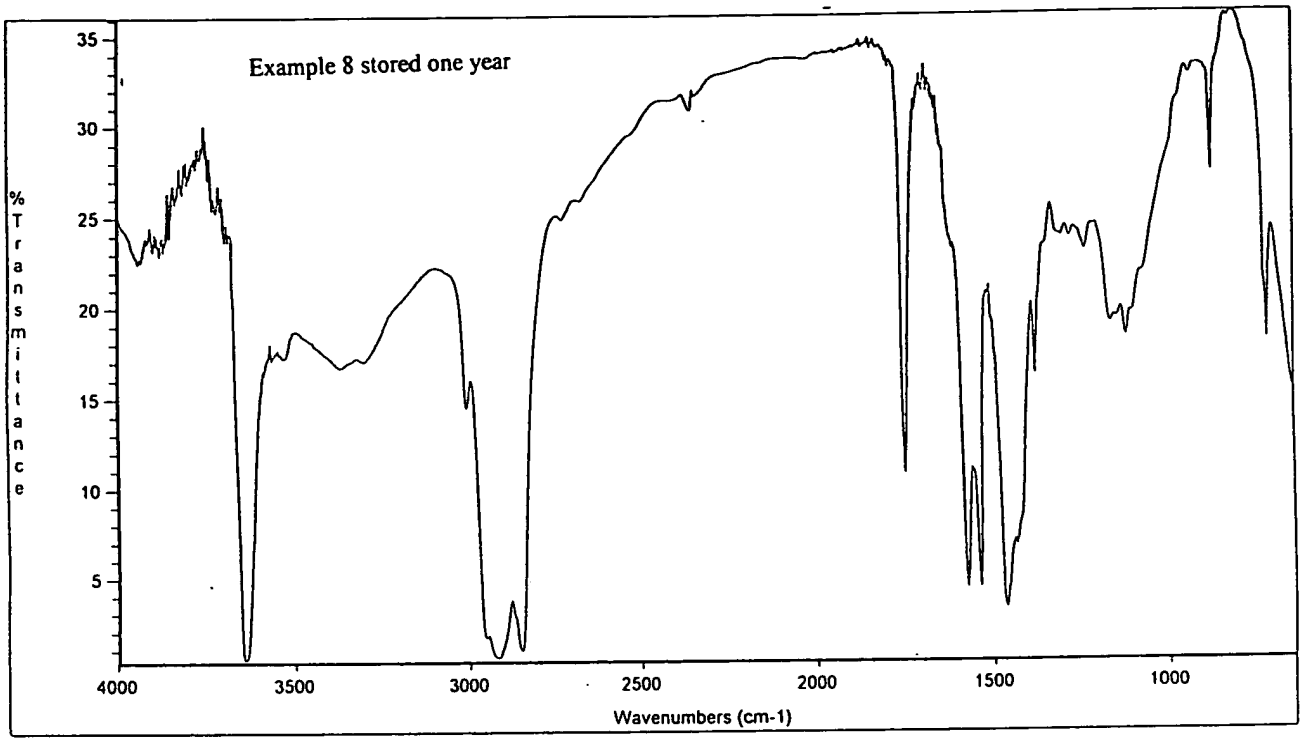
20 g petrolatum (DAB 10), 20 g jojoba oil and 60 g $Ca(OH)_2$ are dispersed and stored in a syringe. The paste has a weak consistence.

The mixture was stored at 40°C for 15 months. IR spectra were taken immediately after preparation and after 15 months storage at 40 °C.

As shown in figure 2 the absorption between 15000 and 1600 cm^{-1} increased very little indicating a small degree of saponification although the paste was stored for a longer time at higher temperature.

(Dr. sc Rainer Lück)

Figure 1


Example 8 stored one year
%Transmittance
35
30
25
20
15
10
5
4000
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)

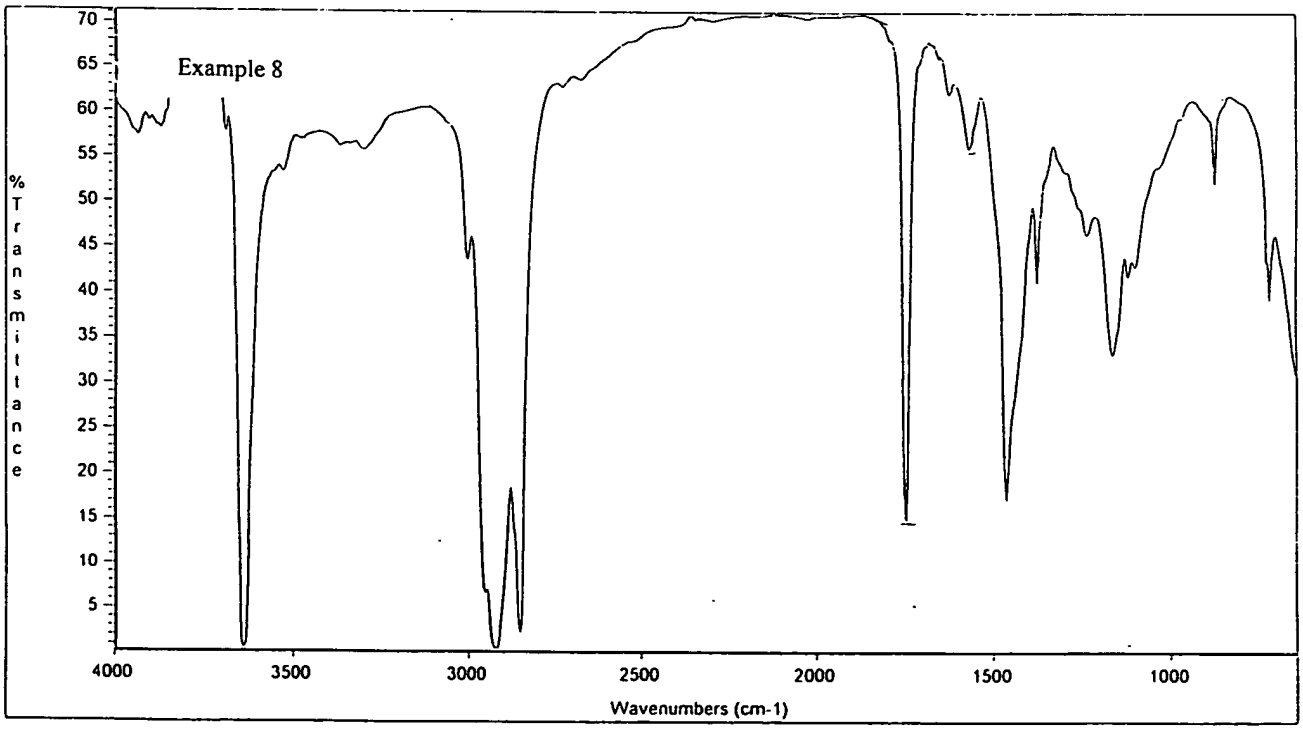
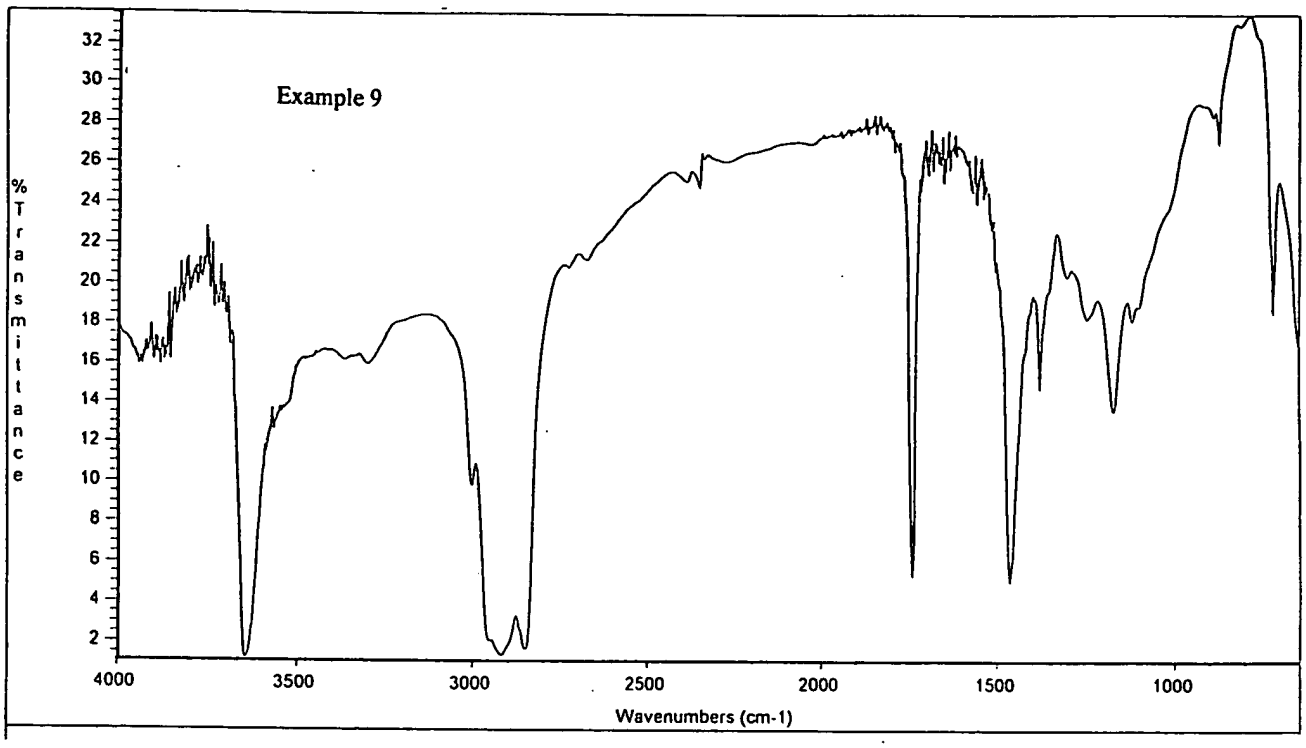
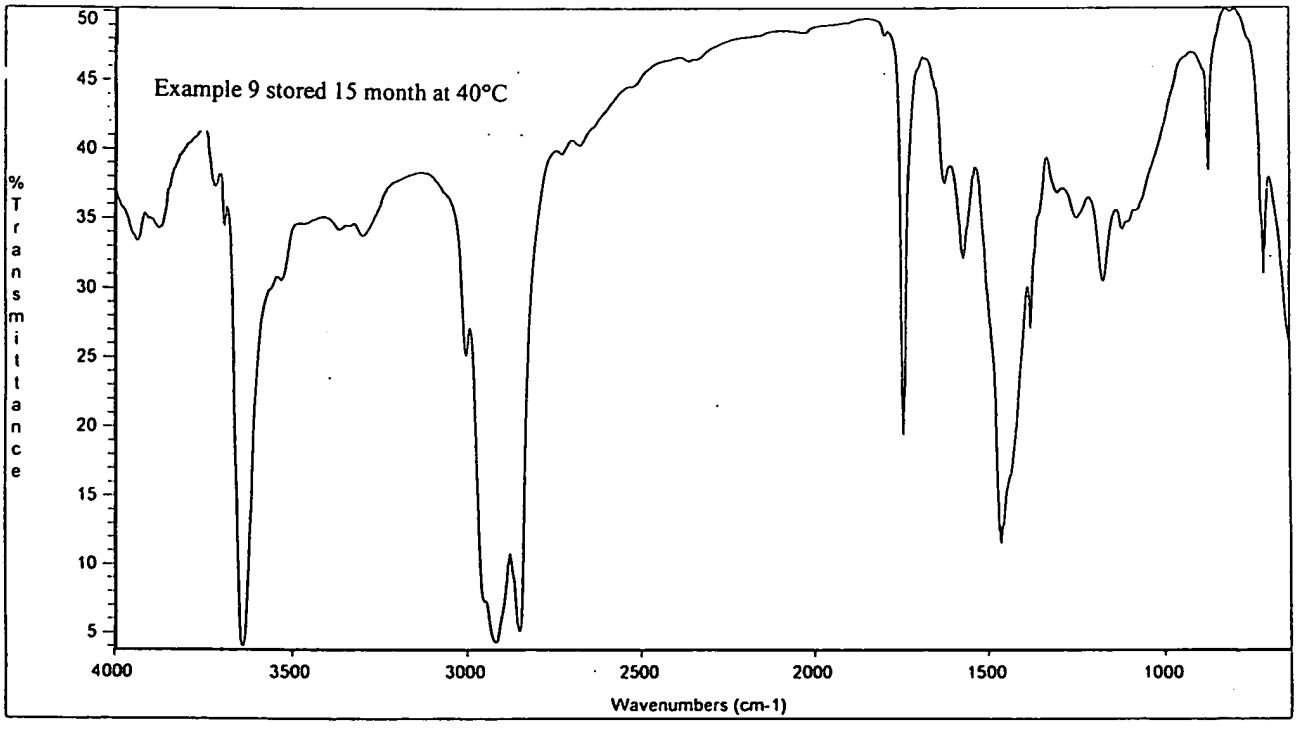

Example 8
%Transmittance
70
65
60
55
50
45
40
35
30
25
20
15
10
5
4000
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)

Figure 2


Example 9
% Transmittance
32
30
28
26
24
22
20
18
16
14
12
10
8
6
4
2
4000
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)


Example 9 stored 15 month at 40°C
% Transmittance
50
45
40
35
30
25
20
15
10
5
4000
3500
3000
2500
2000
1500
1000
Wavenumbers (cm-1)